

## Clinical Process Instruction

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### Organ Allocation System Downtime Process Instruction

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#### Purpose:

The Organ Allocation System (OAS) is supported by core infrastructure components (hosting and storage) and a sign on for user authentication.

The OAS will undergo planned maintenance to implement change requests, perform updates, fix bugs, security patches and program enhancements. During scheduled maintenance, the system will be offline and the functionality listed below is unavailable.

An unplanned OAS outage occurs if the core components or the authentication services are unexpectedly not responding and TGLN's ability to complete processes within their workflow is impacted.

During a planned or unplanned outage, the following OAS functionality may be unavailable:

- Recipients and waitlists cannot be created or updated.
- Donors cannot be added to the system or updated.
- Allocations cannot be run.
- Recovery, transplant, and post-transplant information cannot be entered.
- Data exchanges with integrated systems (e.g. Canadian Transplant Registry (CTR), Donor Management System (DMS)) cannot be performed.

If the sign on and authentication system is down, users cannot log into the OAS.

Information related to planned or unplanned OAS downtime will be communicated to all OAS users by Ontario Health – Service Desk.

This document provides a framework and guidelines for the clinical business continuity process during a planned or unplanned outage of OAS or the sign on and authentication system.

#### Process:

##### Planned OATS Downtime

1. The Clinical Services Coordinator (CSC) Team Lead will ensure that all active donor cases are pushed to the OAS and any allocations that are able to be run are run and the reports saved offline prior to the scheduled downtime.
2. At the scheduled maintenance time, the OAS is taken offline. If the CSC requires the National Organ Waitlist (NOW) during the maintenance window they will contact CTR Customer Support to obtain a copy of the NOW.

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3. The Referral Triage Coordinator (RTC) and CSC will continue to register new donor referrals in the DMS. New donor referrals will be pushed to the OAS as required after the maintenance window is complete.
4. If a Transplant Program wishes to register a high status recipient the CSC will register the recipient as per *OPI-9-103 Business Continuity – Exchanging Recipient and Donor Data with Canadian Transplant Registry*.
5. If an out of province (OOP) offer is made to an Ontario recipient during the maintenance window the CSC informs the OOP Organ Procurement Organization (OPO) that the OAS is undergoing maintenance and that a response may take longer than usual. The CSC may choose to assess the organ based on quality and make interest calls to programs.
6. All OAS users will be notified by Ontario Health-Service Desk when the OAS has been restored to service or if the planned outage is taking longer than initially communicated.
7. Organ allocation for cases that did not have an allocation run in the OAS prior to the planned outage should, if possible, wait until the OAS is back online. If the circumstances of a case mean that allocation cannot wait until the OAS is back online, the CSC will follow the instructions in the **Offline Organ Allocation Process** section.

#### Unplanned OAS Downtime

8. If a Transplant Program wishes to register a high status recipient the CSC will register the recipient as per *OPI-9-103 Business Continuity – Exchanging Recipient and Donor Data with Canadian Transplant Registry*.
9. If a Transplant Program wishes to register or update a non-high status recipient, the information will be entered in the OAS when the system is back online.
10. Ontario organ waitlist and allocation data is exported from the OAS hourly. During an unplanned outage when organ allocation must proceed, the CSC obtains the most recent version of the offline Ontario waitlists and allocations from the TGLN Service Desk. Only allocations that were run prior to the unplanned downtime will be available offline.
11. When making organ offers while the OAS is offline, the CSC will inform Transplant Programs that the offer is being made as part of the offline allocation process and will provide programs with a copy of the offline Ontario waitlist report for the organ being offered.
12. The CSC will record all offers and responses in the clinical notes of the donor chart in the DMS.
13. While the OAS is offline, virtual cross match (VXM) functionality will be unavailable. The CSC will obtain a copy of the donor HLA typing in PDF format from the donor HLA lab. When a VXM is

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required, the CSC will provide the recipient HLA lab with a copy of the donor HLA typing and the lab will perform a manual VXM between the donor and potential recipient.

14. Once OATS is online, the CSC or Clinical Specialist will enter any offer and response information in OATS for organs that were offered during the downtime.

#### Offline Organ Allocation Process

15. For any organ where an allocation recommendation is available, organs will be offered as per the allocation recommendation. For all other organs, offers will be made manually using the NOW and offline Ontario waitlists as outlined in the organ specific processes below.

#### Heart Allocation

16. The CSC will obtain a copy of the NOW list from CTR to identify any status 4 or 4S recipients nationally. Note: if the donor HLA typing was not already in CTR before OATS went offline, the donor must first be manually registered in CTR as outlined in *OPI-9-103 Business Continuity – Exchanging Recipient and Donor Data with Canadian Transplant Registry* and the HLA typing manually entered into CTR by the donor HLA lab.
17. CSC will first notify an Ontario heart transplant program that a 'heart is available' as follows:
  - 17.1. For donors < 19 years old, the CSC will first notify The Hospital for Sick Children (HSC).
  - 17.2. For donors ≥ 19 years old, the CSC will first notify the Ontario adult heart Transplant Program with the recipient with the highest status and longest wait time.
18. The CSC will also notify all OOP programs with eligible status 4 and 4S recipients that “a donor heart is available”. The CSC will send a copy of the donor HLA to the OPO for OOP offers. If multiple programs are interested in the heart a deferral discussion will occur, physician to physician, in a timely manner. The decision to defer an Ontario heart to an OOP recipient will be made by the Ontario program with the recipient with the highest status and longest wait time.
19. If the heart is not accepted for a high-status heart recipient, the CSC will offer the heart to Ontario transplant programs as follows:
  - 19.1. Donors < 19 years old:
    - 19.1.1. The CSC will offer the heart to The Hospital for Sick Children (HSC). HSC will evaluate the heart offer and the offline waitlist and identify any suitable recipient(s) (considering function, medical and social history, ABO, size, etc.).

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19.1.2. The CSC will contact the recipient HLA lab to perform a VXM for any recipient(s) identified by the transplant program as a suitable match.

19.1.3. If HSC declines the donor heart for the program, the CSC will follow the steps outlined for donors  $\geq$  19 years old.

19.2. Donors  $\geq$  19 years old:

19.2.1. The CSC will offer the heart to all Ontario heart transplant programs with active recipients on the waitlist. Each program will evaluate the heart offer and the offline waitlist and identify any suitable recipient(s) (considering function, medical and social history, ABO, size, etc.).

19.2.2. The CSC will contact the recipient HLA labs to perform a VXM for any recipients identified by transplant programs as a suitable match. The CSC will use the *Offering Rules for Hearts – Virtual Cross Match* to rule in or out recipients with a positive VXM.

19.2.3. If there is more than one suitable recipient remaining after step 19.2.2. is complete, the interested transplant programs will participate in a conference call to discuss allocation. Required participants on the conference call are the responsible physicians from all transplant programs interested in the heart, TGLN CMO – Transplant and the CSC. The decision of who to allocate to will ultimately be made by the CMO – Transplant with consideration for recipient status, wait time and list date.

### Liver Allocation

20. During offline liver allocation, the locality rule will not be applied.

21. The CSC will obtain a copy of the NOW list from CTR to identify any 3F or 4F recipients nationally.

22. The CSC will first offer the liver to 4F recipients in Ontario, regardless of ABO. If there are multiple Ontario 4F recipients, the CSC will offer to the longest waiting recipient first. If the wait time is equal, the CSC will offer to the recipient with the earlier list date first.

23. If the liver is not accepted for an Ontario 4F recipient, the CSC will then offer to out of province 4F recipients, regardless of ABO. If there are multiple OOP 4F recipients, the CSC will offer to the longest waiting OOP 4F recipient first. If the wait time is equal, the CSC will offer to the recipient with the earlier list date first. No deferral discussion is required if the liver is accepted for an OOP 4F recipient.

24. If the liver is not accepted for a 4F recipient, the CSC will notify all programs with eligible 3F recipients nationally that a 'liver is available'. If multiple programs are interested in the liver, a deferral discussion will occur, physician to physician, in a timely manner.

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25. Donors < 18 years old and < 50 kg:

25.1. If the liver is not accepted for a high status recipient, the CSC will offer the liver to Hospital for Sick Children (HSC). HSC will evaluate the liver offer and the offline waitlist and identify any suitable recipients (considering function, medical and social history, ABO, size, etc.).

25.2. If HSC declines the donor liver for the program, the CSC will follow the steps outlined in step 26.

26. Donors  $\geq$  18 years old; or donors < 18 years old and > 50 kg:

26.1. If the liver is not accepted for a high status recipient, the liver will be offered to all liver transplant programs. The liver transplant programs will evaluate the liver offer and the offline waitlist and identify any suitable recipient(s) (considering function, medical and social history, ABO, size, etc.). If there are multiple suitable recipients, the interested transplant programs will participate in a conference call to discuss allocation. Required participants on the conference call are accepting physicians from all transplant programs interested in accepting the liver, TGLN CMO – Transplant and the CSC. The decision of who to allocate to will ultimately be made by the CMO – Transplant with consideration for ABO, SMC, wait time and list date.

### Lung Allocation

27. Lungs will be offered as an open offer to the Multi-Organ Transplant Coordinator (MOTC). The Toronto General Hospital (TGH) lung surgeon will evaluate the lung offer and the offline waitlist and identify any suitable recipients (considering function, medical and social history, ABO, size, etc.) at either TGH or HSC.

### Small Bowel Allocation

28. Small bowel will be offered as an open offer to the MOTC. The TGH surgeon will evaluate the small bowel offer and the offline waitlist and identify any suitable recipients (considering function, medical and social history, ABO, size, etc.) at either TGH or HSC.

### Kidney and Pancreas Allocation

29. Due to the complexity of kidney and pancreas allocation, the number of recipients on the waitlist and the need for a manual VXM, kidney and pancreas allocation should be postponed until the OAS is online if at all possible.

30. If expedited recovery of kidneys is required during the OAS downtime, consider making kidney interest calls and placing the recovered kidneys on pumps while waiting for the OAS to come back online.

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31. If allocation cannot be delayed allocate kidneys in consultation with TGLN CMO-Transplant using the following guiding principles:

31.1. The CSC will first offer the kidneys to any medically urgent recipients with identical or compatible ABO.

31.2. Next, the CSC will call CTR Customer Support and request they run an HSP kidney allocation and send a copy of the matched HSP recipients. Note: if the donor HLA typing was not already in CTR before OATS went offline, the donor must first be manually registered in CTR as outlined in *OPI-9-103 Business Continuity – Exchanging Recipient and Donor Data with Canadian Transplant Registry* and the HLA typing manually entered into CTR by the donor HLA lab. The CSC will offer the kidneys to any HSP recipient(s) identified by CTR. If there are multiple HSP kidney recipients identified, both kidneys will be offered to HSP recipients.

31.3. Next, the CSC will offer the kidneys to any active multi-organ recipients with identical or compatible ABO. Multi-organ recipients are defined as any cluster of kidney with another organ (excluding kidney/pancreas). The kidney should only be offered to multi-organ recipients if the clustered organ is available. If there are multiple suitable recipients, the interested transplant programs will participate in a conference call to discuss allocation. Required participants on the conference call are accepting physicians from all transplant programs interested in accepting the kidneys, TGLN CMO – Transplant and the CSC. The decision of who to allocate to will ultimately be made by the CMO – Transplant with consideration for cPRA, ABO, wait time and list date.

Note: this step does not apply to donors < 4 years old.

31.4. Next, if the donor is < 35 years old and > 4 years old the CSC will make an open kidney offer to HSC if there any active HSC kidney recipients with identical or compatible ABO. HSC will evaluate the kidney offer and the offline waitlist and identify any suitable recipients (considering function, medical and social history, ABO, size, etc.).

31.5. Next, if the pancreas is suitable the CSC will offer the pancreas +/- kidney to all programs with active kidney/pancreas cluster or pancreas (whole) recipients with identical or compatible ABO. Transplant programs will evaluate the pancreas and/or kidney offer and the offline waitlist and identify any suitable recipients (considering function, medical and social history, ABO, size, etc.). If there are multiple suitable recipients, the interested transplant programs will participate in a conference call to discuss allocation. Required participants on the conference call are accepting physicians from all transplant programs interested in accepting the kidneys, TGLN CMO – Transplant and the CSC. The decision of who to allocate to will ultimately be made by the CMO – Transplant with consideration for cPRA, ABO, wait time and list date.

31.6. Next, the CSC will offer the kidneys to the local kidney program. The local program will evaluate the kidney offer and the offline waitlist and identify any suitable recipients.

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31.6.1. If there is a region with multiple programs (i.e. Toronto), the kidney will be offered to all programs in the local region and if there are multiple suitable recipients, the interested transplant programs will participate in a conference call to discuss allocation. Required participants on the conference call are accepting physicians from all transplant programs interested in accepting the kidneys, TGLN CMO – Transplant and the CSC. The decision of who to allocate to will ultimately be made by the CMO – Transplant with consideration for cPRA, ABO, wait time and list date.

31.7. If the local program(s) are unable to accept both kidneys, the CSC will offer to the provincial recipient with the highest allocation points and a cPRA < 50%. The CSC will repeat this step until the kidneys are accepted or declined by all programs.

#### Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
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No Records

#### References:

- *Waitlist, Organ Offers and Allocation Policies Document, TP-9-100*
- *Business Continuity – Exchanging Recipient and Donor Data with Canadian Transplant Registry, OPI-9-103*